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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,668	RITCHIE ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-11,13,15,16 and 18-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-11,13,15,16 and 18-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/29/09 was filed after the mailing date of the last Office Action on 2/3/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9-11, 13, 15, 16, 18, 23-39 rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn et al (USPN 5,753,614 hereafter '614) in view of Huber et al (USPN 3,758,682 hereafter '682) and Robertson et al (USPN 4,939,135 hereafter '135). The claims are drawn to a topical cleansing formulation comprising a chelating agent, surfactant, pH buffer and an antibacterial.

The '614 patent discloses a topical biocidal composition (abstract). The formulation comprises chelating agents such as EDTA in a concentration of approximately 20 mMol (col. 2, lin. 20-25). The formulation further discloses the inclusion of surfactants such as cocamidopropyl betaine, where the surfactants are present in an amount of about 1% (col. 2, lin. 55-58, example 4, TABLE 4). The formulation comprises 50 mMol of a Tris buffer that maintains the pH of the formulation from 5-9, preferably 7.8 (col. 4, lin. 10-25, examples). Nisin is present as an antibacterial agent is present in a concentration from 10-300 μg/mL (examples). Each of the components, the buffer, chelator, surfactant and biocide are shown to be synergistically related to one another in the reduction of bacterial populations (examples). The compositions are useful against Gram positive or negative infections in various surfaces such as skin, or food products (col. 2, lin. 25-30, col. 3, lin. 5-30). The formulation can have a liquid carrier and be applied to medical dressings as a wound treatment (col. 3, lin. 10-15). The formulation can be applied to the skin, this skin would include hair inherently (col. 3, lin. 10-20).

The reference differs from the instant claims by disclosing a different Tris buffer compound. However a compound is used in the same concentrations as the instant claims and for the same purpose of maintaining the pH of the formulation in a specific range. The inclusion of these compound is common in the art and can be seen in the '682 patent.

The '682 patent discloses a formulation useful in wound healing comprising a buffer solution comprising tris(hydroxymethyl) amino methane (col. 13, lin. 25-30). Further the composition can be administered orally contacting the oral mucosa (col. 24, lin. 19-53). The artisan of ordinary skill would have been motivated to include these components in order to improve the stability of the wound treating formulation.

As discussed above the '614 patent discloses a topical biocidal composition comprising a biocide, chelator, buffering agent and surfactant. The reference is silent to any additional anti-inflammatory agents, however the composition can be applied to wound dressings for treatment of wounds, and as such anti-inflammatory agents would be an obvious addition to decrease inflammation during treatment. The addition of anti-inflammatory agents, specifically the agents of the instant claims would have been well within the level of skill in the art as seen in the '135 patent.

The '135 patent discloses a wound healing formulation and method of applying the formulation to an ocular injury (abstract). The formulation comprises anti-inflammatory agents such as dexamethasone and antimicrobials such as neomycin and vancomycin (col. 4, lin. 60-65; col. 9, lin. 60-68). The active agents are in a concentration from 0.5-1.0% of the total formulation (col. 8, lin. 1-5). The formulation further comprises chelators and sorbic acid (col. 10, lin. 60-65). The artisan of ordinary skill would be motivated to combine the components of the '614 patent with those of the '135 patent since they both solve the same problem of wound management with cleansing compositions. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Regarding the specific ranges and concentrations of the specific components, it is the position of the Examiner that such limitations would be obvious in view of the prior art. The '614 patent discloses a topical formulation comprising chelator, surfactant, buffer and biocidal

agent, meeting the general conditions of the instant claims. It is the position of the Examiner that the concentrations and ratios are well within the level of skill in the art to optimize in order to arrive at the current invention and to provide a stable formulation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to combine the buffers '682 patents into the cleansing formulation of the '189 patent in order to improve the stability of the cleansing formulation. It would have been obvious to combine these compounds with an expected result of a stable cleansing composition and improve method of cleansing and disinfecting the skin at a wound site.

Claims 1-3, 5, 6, 9, 13, 19-22, 30-32, 34-36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Blackburn et al (USPN 5,753,614 hereafter '614) and Huber et al (USPN 3,758,682 hereafter '682) in view of both Mulder et al (USPN 5,565,189 hereafter '189) and Gehlsen (USPN 6,270,781 hereafter '781). The claims

are drawn to a topical formulation comprising pH stabilizers, detergents, antimicrobial agents, colorants and perfumes.

As discussed above the combination of the ‘614 and ‘682 patent discloses a topical biocidal composition comprising a biocide, chelator, buffering agent and surfactant. The reference is silent to the specific auxiliary components recited in the instant claims. These compounds are common in the art, specifically in topical formulations. Stabilizers improve long term storage while perfumes and colorants add aesthetic appeal and aid in distinguishing the composition from other formulations.

The ‘189 patent teaches a method of cleaning the skin comprising the application of a cleansing composition comprising a carrier, water and aloe vera gel, a pH buffer such as sodium borate, chelators such as EDTA, vitamin E surfactants such as cocamphoacetate and biocides such as hydroxyquinoline (example 1). The method further debriding the wound site, rinsing the composition after it is applied (col. 4, lin. 45-55). The pH of the composition is between pH 6.5-6.8 (col. 4, lin. 3-10). The formulation includes sensitizers that relieve pain (example 1). The artisan of ordinary skill in the art would have been motivated to combine the stabilizers of the '189 patent into the '614 formulation since they both cleans and disinfect the skin.

The ‘781 patent discloses a topical skin composition comprising detergents, antimicrobial agents, perfumes and pigments (col. 8, lin. 6-15; col. 8, lin. 57-65; col. 9, lin. 28-32). The artisan of ordinary skill would have been motivated to include the pigments and perfumes of the ‘781 with the formulation of the ‘614 since they comprise similar components in the same field of endeavor.

One of ordinary skill in the art would have been motivated to combine the components of the '781 and '189 patents into the formulation of the '614 and '682 patents in order to improve the aesthetic properties and long term storage stability of the formulation. It would have been obvious to combine these components with an expected result of an aesthetically pleasing fragrant skin cleansing composition.

Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Blackburn et al (USPN 5,753,614 hereafter '614) and Huber et al (USPN 3,758,682 hereafter '682)in view of Horn (USPN 5,848,700 hereafter '700). The claims are drawn to a kit comprising a skin cleanser and instructions to use the cleanser.

As discussed above the patent combination discloses a skin cleansing formulation comprising chelators, carriers, pH buffers, a detergent and an antimicrobial agent. The reference discloses instructions of the use and application of the skin cleansing composition. The reference discloses method of applying the cleansing to the skin by is silent to a specific kit. The inclusion of a kit is well known in the art and shown in the '700 patent.

The '700 patent discloses a kit comprising instructions for various applications methods inclusion cleansing the skin of burns, cuts, wounds and fractures (claims). It would have been obvious to include the skin cleanser of the '614 patent with the instruction of the '700 since they both endeavor to treat wounds.

One of ordinary skill in the art would have been combine the instructions of the '700 patent with the cleanser of the '614 patent in order to form a kit to ensure proper and safe use of the cleansing formulation. One of ordinary skill in the art would have been motivated to make

the combination with an expected result of a kit comprising a skin cleansing formulation and instructions for proper and safe use that would be accessible to those of ordinary skill it the art.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 9-11, 13, 15, 16, and 18-43 have been considered but are moot in view of the new ground(s) of rejection.

The combination of the '614 patent and the '682 patent does not obviate the instant claims since the '614 patent does not provide a sufficient concentration of EDTA.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It remains the position of the Examiner that the combination of the '614 and the '682 continues to obviate the instant claims. Applicant argues that the '614 patent discloses the inclusion of an additional ion in combination with the EDTA and would not teach the synergistic cooperation of chelating agents and surfactants in order to increase antimicrobial effect. Although the '614 patent teaches that excessive concentrations of EDTA would require a n additional ionic components, the concentration is taught to be below this threshold of 20 mM. The concentration of the EDTA present in the formulation is from 1-20mM, and the chelating compounds are combined with surfactants such as those recited in the claims, cocamidopropyl betaine. The Examples provide a concentration within the range of the instant claims. Further Applicant argues that the preferred embodiment is not taught by the '614 patent. However the

broad claims continue to disclose any chelating agent in a wide range from 2-250 mM, 1-30% cocamidopropyl betaine, a sufficient concentration of a buffer component to maintain the pH from 7-9. The '614 patent discloses EDTA present in a concentration of 20mM, 1% of a surfactant such as cocamidopropyl betaine, a an amount of a Tris buffer sufficient to maintain the pH at 7.8 (col. 4, lin. 20-25). Although silent to a specific synergistic relationship, the concentrations are well within the broad ranges that would result in such a relationship. As such since the same compounds are provided in the same concentrations the same result must occur. Any further modifications within the those ranges would have been obvious optimization of the components, well within in the limits of one of ordinary skill in the art. The '614 patents discloses that a Tris buffer is used but is silent to the specific buffer, while the '682 patent provides the specific buffer. It would have been obvious to include the buffer of the '682 patent in order to maintain the pH of the formulation as recited in the '682 patent. The reference discloses the formulation including the buffer for use in mucosal applications, establishing the level of skill in the art regarding the use of Tris(hydroxymethyl) aminomethane base in a mucosal application where the pH is to be maintained from 7-9. For these reasons the claims remain obviated.

The remaining arguments are based on the newly amended claims are moot in view of the new rejection. However the remaining supporting reference continues to provide auxiliary support for the Blackburn '614 patent. It remains the position of the Examiner that it would have remained obvious to include the anti-inflammatory agents of the '135 patent, the perfumes and stabilizers of the '189 and '781 patent and included these components together into a kit as described in the '700 patent. It would have been obvious combine active agents in order

to increase the effectiveness of the formulation, and also added perfumes in order hide harmful chemical smells as well as include stabilizers to increase the shelf life of a formulation. These would have been combined into a kit in order to provide clear instructions on safe use for the wound healing formulation. For these reasons the claims remain obviated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618